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EXAMINER

VRETTAKOS, PETER J

ART UNIT PAPER NUMBER

3739

DATE MAILED: 12/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/823,903

Applicant(s)

BALBIERZ ET AL.

Examiner

Peter J Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-7,9-12,14,22-25,28,29,31,32,34,42-50,52-74,79 and 80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-7,9-12,14,22-25,28,29,31,32,34,42-50,52-74,79 and 80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All. b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The instant action is **final**. The rejections below include prior art that was unearthed in a recent update search performed by the Examiner.

Benaron et al. (US 5,769,791) is presented below to address changes to the claims in Amendment C filed 10-14-03.

It's noted that Application number US 09/823,910 consists of claims similar to those in the instant application. However, the instant claims are apparatus claims, whereas the referred application claims are toward a method of use. A restriction requirement would have been submitted had all claims been combined in a single case due to significant differences of the apparatus and method of use claims. Therefore, no Double Patenting requirements are asserted in the instant or referred application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1, 5-7, 9-12, 14, 22-25, 28-29, 31-32, 34, 42-44, 49, 50, 79 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough in view of Benaron et al. ('609) and further in view of Benaron ('791).

Gough et al. (Gough) discloses an apparatus for detecting and treating a tumor comprising:

Independent claims 1, 14, and 42(spectral profile limitation included in Benaron discussion below)

an elongated delivery device (figure 3; 10) including a lumen (14);

a deployable sensor array (24, col. 6:34-41 – can be “optical”) including a plurality of resilient members (18 and 16) each having a tissue piercing (fig. 2c, 16) distal portion deployable from a compacted state with curvature (figure 3), the sensor array having a geometric configuration (figure 3) adapted to volumetrically sample tissue at a tissue site or multiple tissue sites to differentiate or identify tissue including tumor boundaries or boundaries between healthy and abnormal tissue (col. 4:63-67, **col. 6:23-34**) at the tissue site(s) during an energy delivery interval, as well as adapted to change direction of travel responsive to tissue applied forces;

electrodes (12,14,16, col. 4:42-44) coupled to (or comprising) the resilient members (18);

an RF energy source (20, col. 6:7-10);

logic resources (38, col. 10:40-46 and 50, col. 11: 5-8);

a handpiece (obvious) and an introducer or rigid advancement device (patented claim 36).

Dependent claims

Re: claim 5, Gough discloses a multiplexer (46) to measure and compare parameters at the numerous sensors (24) each providing measurements including temperature from different tissue volumes.

Re: claims 6-7, Gough discloses logic resources (38, col. 10:40-46 and 50, col. 11: 5-8) that in conjunction with the sensors (24) differentiate tissue types (col. 6:28-34).

Re: claims 9-11, Gough discloses a monitor /display device (36).

Re: claim 12, Gough discloses the ability through sensors and logic resources the ability to identify a clinical endpoint (col. 6:31-32, iii).

Re: claims 22-25, Gough discloses an optical fiber (col. 6:37-38) connected to a light source (inherent). Also see col. 6:14-18.

Re: claims 28-29, Gough discloses temperature sensors (24) that can detect tissue ablation volume (col. 6:28-33).

Re: claim 34, Gough discloses detection of cancerous and non-cancerous tissues ("tumor boundaries"; col. 4:63-67, **col. 6:23-34**).

Re: claim 43-44, and 49, Gough discloses a fiber optic emitter (24, col. 6:38). Optimal placement of the emitter as well as optimal frequency emittance would be obvious through routine experimentation.

Re: claim 50, Gough discloses an infusion port and cooling element (27, fig. 2(b).)

Re: claims 79 and 80, Gough discloses a handpiece (inherent) and advancement devices (introducers, patented claim 36, col.5: 5-10). Secondary advancement devices are also disclosed (16).

Gough neglects to disclose a spectral profile measurement.

Benaron et al. (Benaron) discloses an analogous tumor treatment method and apparatus comprising the use of a spectrophotometer (col. 8:42-53; col. 9:13-20), permitting spectral profile measurements of targeted tissue. The Applicant also uses a spectrophotometer to undertake spectral profile measurements as submitted in the Specification page 16 line 13. Further, Benaron discloses logic resources (26, col. 9:16-20 and 147, col. 11:50-61)

Re: claim 31, Benaron discloses detection of structural and chemical cell changes during ablation.

Gough and Benaron et al. ('609) neglect to expressly disclose an optical sensor connected to function as an emitter and detector, as well as an optical switching device.

Benaron ('791) is presented in response to the new issue introduced into independent claims 1 and 57 (an optical sensor and switch for alternating emitting/detecting function). Benaron discloses in an analogous device, an optical sensor (995, figures 9 and 10) connected to function as an emitter (43) and a detector

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(947), and optical switching device (994, figures 9 and 10). Corresponding disclosure is found in columns 25 and 26.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Gough in view of Benaron by including as a design expedient a spectrophotometer. The motivation to do so would be as posited by Benaron in col. 8:49-53, "to minimize risk of collateral damage or incomplete treatment, and to maximize success..."

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Gough in view of Benaron and further in view of Benaron et al. by including as design expedients an optical sensor (995, figures 9 and 10) connected to function as an emitter (43) and a detector (947), and optical switching device (994, figures 9 and 10). The motivation to do so would to provide a tool capable of detecting the type of tissue being or to be treated.

2. Claims 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough in view of Benaron and further in view of Benaron ('791) and further in view of Hoey et al. ('722).

Gough and Benaron neglect to disclose baseline measurements.

Hoey et al. (Hoey) discloses an analogous electrode tissue ablation method in which *baseline impedance measurements* (232) including reference signals are taken

as depicted in figure 11. Further, Hoey discloses comparing (226,240) impedance measurements throughout the surgery and adjusting (228,246) energy delivery parameters (RF power), accordingly, which further affect tissue ablation time and volume.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Gough in view of Benaron and further in view of Benaron ('791) and further in view of Hoey by including as a method step, that of obtaining and using impedance measurements to guide effective surgery. The motivation would be to "safeguard the patient and the apparatus," as submitted in Hoey col. 23:20-21.

3. Claims 52-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough in view of Benaron and further in view of Benaron ('791) and further in view of Ben-Haim et al. ('310).

Gough and Benaron do not disclose sensors that detect fluorescent markers.

Ben-Haim discloses an analogous ablation device with sensors (92) that detect fluorescent markers (col. 9:52-59).

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Gough in view of Benaron and further in view of Benaron ('791) and further in view of Ben Haim by including sensors that detect contrast, flourescence, cell activity, etc. The motivation would be to provide the

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surgeon further insight with regards to the surgical milieu such as cell activity and function during surgery, as well as to help differentiate different tissue types.

Response to Arguments

Applicant's arguments with respect to all claims have been considered but are moot in view of the new ground(s) of rejection. New art is presented above.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746 7013 for regular communications and 703 746 7013 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0858.

Pete Vrettakos
December 19, 2003




MICHAEL PEFFLEY
PRIMARY EXAMINER